



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Southwest Import District
Southwest Region
3310 Live Oak Street
Dallas, Texas, 75204

Telephone: 214-655-5310
FAX: 214-655-5330

WARNING LETTER

Ref: 2001-SWID-WL-2

February 1, 2001

FEDERAL EXPRESS

T & G Sales
Jesus Tiscareno, Owner
1536 Clavelita Place
San Diego, CA

Dear Mr. Tiscareno,

On January 24, 2001 we attempted to examine three shipments of avocado pulp products identified with entry numbers KD5-1102653-6; KD5-1102676-7; KD5-1102687-4 that are currently being detained without examination by the Food and Drug Administration (FDA). The shipments were offered for import (imported) into the United States by your firm on January 12, 14, and 15, 2001. As explained in our detention notices, these entries (dated January 12 or January 17) were being detained without physical examination because they may be contaminated with *Listeria monocytogenes*, a pathogenic microorganism that may render this product injurious to health. When we attempted to examine these shipments, we found two of these entries completely unavailable and entry KD5-1102653-6 was missing [REDACTED] pails and [REDACTED] cartons from the original entry, which contained [REDACTED] pails, and [REDACTED] cartons. This is a violation of 21 USC 381(a) and 21 CFR Section 1.90 that requires the importer to hold an imported article and not distribute it pending receipt of the results of examination of a sample.

This is the third time we have determined you have failed to hold shipments subject to detention and/or FDA examination.

Specifically, Entry KD5-1101653-7 was sampled on October 27, 2000, at which time you were notified that a sample had been collected and the shipment was to be held intact pending the results of the analysis. The entry was detained on November 30, 2000 based on the FDA lab analysis that found *Listeria monocytogenes* in the product. On December 19, 2001, we attempted to verify the entry was intact and found that [REDACTED] of the original [REDACTED] pails were missing.

Furthermore, on January 12, 2001 we attempted to examine 15 entries of the same avocado pulp product that were detained without physical examination based on the FDA lab findings on entry KD5-1101653-7 and the potential for contamination with *Listeria monocytogenes*. These shipments were entered under entry numbers KD5-1102218-8; KD5-1102272-5; KD5-1102286-5; KD5-1102304-6; KD5-1102334-3; KD5-1102351-7; KD5-1102391-3; KD5-1102402-8; KD5-1102402-8; KD5-1102405-1; KD5-1102406-9; KD5-1102406-9; KD5-1102407-7; KD5-1102418-4; KD5-1102429-1; KD5-1102440-8; KD5-1102452-3; KD5-1102463-0; KD5-1102478-8; KD5-1102487-9; KD5-1102498-6; and KD5-1102512-4. None of these entries were available for examination and according to statements made by your Sales Manager to our Investigators had been sold and distributed to your customers.

We are concerned with your apparent disregard to our Notices of FDA Action especially after advising you of the requirements to hold product via FDA Notices Of Action and during a meeting in our office on December 19, 2000 with your broker present and during telephone conversations with our Investigators.

As a result, we have recommended that the U.S. Customs Service require that future shipments of food imported into the U.S. by your firm be held in secured storage. If required, secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

In addition, we are requesting U. S. Customs Service to order redelivery of the shipments.

Within 15 working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct this violative situation, including an explanation of each step being taken to prevent recurrence.

Your reply should be addressed to: Vincent F. Iacono, Compliance Officer
U.S. Food and Drug Administration
Otay Mesa Port of Entry
9777 Via De La Amistad #131
San Diego, CA 92154

Should you have any questions related to this letter, you may also contact Mr. Iacono at 619-661-3273 ex 229.

Sincerely,



Robert J. Deininger
Southwest Import
District Director